



February 14, 2007

The Honorable Paul Condino
Chairman, House Judiciary Committee
Michigan House of Representatives
State Capitol
Lansing, Michigan 48909-7514

RE: **House Bill 4044**

Dear Chairman Condino:

On behalf of the Consumer Healthcare Products Association (CHPA)', I am writing to express our opposition to House Bill 4044, which would repeal important reforms to Michigan's product liability laws impacting nonprescription or over-the-counter medicines that have been approved by the U.S. Food and Drug Administration (FDA) and manufactured and labeled according to FDA requirements. Enacted in 1996, this law made significant improvements to the manner in which punitive damages are awarded in cases involving products that comply with federal standards. Accordingly, CHPA strongly urges the defeat of HB 4044.

Current law in Michigan provides that punitive damages may not be awarded against a manufacturer of a drug product where that product conforms in all material respects with the requirements of state and federal law governing its manufacturing, packaging and labeling. Such is the case with important nonprescription, over-the-counter medicines that are manufactured and distributed in this state. Where the formulation, packaging and labeling of an over-the-counter medication has received approval from the FDA, a plaintiff would be limited to compensatory damages for any harm allegedly caused by the product, unless the defendant has engaged in illegal activity or withheld material information from the government regulating agency.

The Michigan statute has been particularly important to CHPA members because of the injustice that arises when a manufacturer who complies with all federal and state laws and regulations and is nevertheless subjected to the possibility of punitive damages.

' CHPA is the 125-year-old trade association which represents manufacturers -- both large and small -- of nonprescription or over-the-counter (OTCs) medicines such as cold remedies, antacids, pain relievers, and many others. The Association's members account for approximately 95 percent of all OTC medicines sold in the United States. A nonprescription drug is one that the U.S. Food and Drug Administration has found to be safe and effective for direct consumer use based on the required label directions and warnings.

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Nonprescription medicines are among of the most heavily regulated types of consumer products in the world. The FDA thoroughly reviews all aspects of manufacturing and labeling and demands strict compliance with its regulations. Despite these rigorous government standards, OTC medicine manufacturers can be subject to enormous punitive damages awards by juries who second-guess government and other scientific experts. Even where a product conforms in all respects to the FDA requirements, juries can deem that conduct to be "reckless" and award punitive damages against the manufacturer. The 1996 law prohibits punitive damages in such cases.

The potential of unwarranted punitive damage verdicts will significantly increase the costs and reduce the availability of insurance for manufacturers in this state. It will hamper additional research into new medicines and deter the development of new products. It will also unnecessarily raise the costs of healthcare for all consumers through the increased cost of manufacturing and distributing nonprescription medicines. As part of a strategy to preserve the economic standing of all the citizens of Michigan, the government standards defense, as enacted in Michigan in 1996, should be preserved.

We urge the defeat of HB 4044.

If I can be of any further assistance in this matter, please do not hesitate to contact me. Thank you for your careful consideration of our views.

Very truly yours,

Kevin J. Kraushaar
Vice President, Government Relations